LONG CHAIN ALCOHOLS PROVIDED IN EDIBLE OILS

5   Related Applications

This application is being concurrently filed with two additional applications. These related applications are entitled Encapsulated Long Chain Alcohols, US Serial Number yy/yyy,yyy (Attorney Docket MCP-234) and Long Chain Alcohols Admixed in Sterol Compounds, US Serial Number zz/zzz,zzz (Attorney Docket MCP-235), the contents of these applications incorporated by 10   reference as if set forth in their entirety.

Field of the Invention

The present invention describes a method of obtaining uniform distribution of a long chain 15   alcohol or a mixture of such alcohols in a comestible product by dissolving or suspending the long chain alcohol in an edible oil.

Background of the Invention

20   Long chain alcohols are known to have beneficial effects on human health. Researchers have reported that a blend of long chain alcohols obtained from sugar cane wax was effective in lowering serum cholesterol in rats. Sho, H., Chinen, I., and Fukuda, N., J. Nutr. Sci. Vitaminol. 30:553 (1984). In addition, US Patent No. 5,856,316 discloses the use of a mixture of long chain alcohols from sugar cane wax for lowering serum cholesterol in humans.

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From the above disclosures it is apparent that long chain alcohols have important properties for improving the health of humans and animals. These beneficial properties include improving stamina, lowering blood cholesterol levels, and decreasing platelet aggregation. One desirable route for ingesting these alcohols is in food or beverage products. However, these long chain alcohols are 30   very insoluble in water, and the very small amounts of these long chain alcohols needed to produce beneficial health effects makes content uniformity of long chain alcohols in a dry blending operation very difficult to achieve. Therefore, a means is needed for incorporating these long chain alcohols into food or beverage products in a manner that yields a uniform and consistent distribution of these materials in the comestible product.

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Expensive and difficult measures have been disclosed to overcome these problems. For example, EP 801904 A1, describes the use of long chain alcohols (defined as alcohols having more

than 20 carbon atoms) in continuous fat phase compositions containing particulate sweeteners. The incorporation of the long chain alcohols at about 0.1% to about 0.4% was reported to decrease the viscosity of confectionery coatings made with this composition. All of the described compositions contained a particulated sweetener in addition to a chocolate material and a vegetable oil.

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Similarly, WO 98/47385 discloses a fat emulsion with a blend of emulsifiers created by the blending of a partial glyceride with a phospholipid and a long chain alcohol having a chain length of greater than C_{20}. The total weight of the glyceride and phospholipid in the composition must be greater than about 0.02 weight percent.

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Despite the teachings of these disclosures, there is an ongoing need to easily incorporate long chain alcohols into food products so that the advantageous effects of these alcohols can be achieved.

15 ### Summary of the Invention

The present invention provides a method of providing a desirable distribution of long chain alcohols in a food or beverage product. More specifically, this process comprises dissolving or suspending the long chain alcohol in an edible oil, and then incorporating this edible oil into a food 20 or beverage product. In one embodiment the present invention is a method for preparing a long chain alcohol in an edible oil material comprising: providing an edible oil substantially free of medium chain triglycerides composed of C_8-C_{10} triglycerides and less than about 12 weight percent linolenic acid; providing a long chain alcohol; admixing said edible oil and long chain alcohol in the presence of an energy source such that the long chain alcohol is admixed in the oil; said long chain 25 alcohol/edible oil admixture is stable and substantially free of an emulsifier or surfactant and having a viscosity of less than about 200 centipoise as measured at 70 °F at 60 revolutions per minute.
A second embodiment of the invention provides the composition made by the method of the invention. In a third embodiment the composition of the present invention is employed to reduce the cholesterol level of a vertebrate that consumes an effective amount of the composition.

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Detailed Description of the Invention

The present invention provides a method for incorporating long chain alcohols into an oil matrix without the need to add emulsifiers, surfactants or penetrant enhancers. The method includes 35 the use of heat or mechanical energy or other suitable energy sources in order to make the long chain alcohols soluble in the lipid matrix. In a preferred embodiment the lipid matrix is an oil, preferably

an oil derived from a vegetable source. Suitable oil sources include sunflower, safflower, corn, soybean, canola, mixtures of these oils and the like.

As used herein, long chain alcohols are understood to include saturated and unsaturated alcohols which contain more than about 90 weight percent C_{20} or longer, primarily aliphatic alcohol materials. For the greatest health benefit it is preferred that the long chain alcohols be predominately, greater than 50 weight, percent octacosanol (C_{28}), preferably more than 65 percent and more preferably greater than about 70 weight percent. As used herein policosanol is understood to be a mixture of long chain alcohols ranging from C_{20} to C_{36} preferably with greater than 65 weight percent C_{28}. Common distribution and concentration ranges of the various components of policosanol are found in US Patent 5,856,316, the contents of which are incorporated by reference as set forth in its entirety. These long chain alcohols are available from various natural sources, most preferably from sugar cane wax. The long chain alcohols can also be synthesized using techniques well known in the art.

Policosanol is soluble at about 160 – 180 °F in suitable lipid matrices such as vegetable oils and fat-soluble emulsifiers, vitamins and the like. Suitable methods for incorporating policosanol or other long chain alcohol into the oil, include heating by conventional means such as: heating elements or open flame; radiation sources and other ultrasonic wave generating equipment; as well as mechanical means such as agitation, homogenization, and the like.

In a preferred embodiment of the present invention, the long chain alcohol is ground into a microcrystalline form in order to improve the stability of the oil/long chain alcohol mixture. Suitable grinding techniques include hammermill, cryogenic rotary mills and the like. The particle size of the ground material is less than about 100 microns, preferably from about 20 to about 80 and most preferably from about 30 to about 60 microns.

Typically the level of long chain alcohol incorporated into the oil is from about 0.1 to about 5 percent, preferably from about 0.5 to about 3 and most preferably from about 0.8 to about 2 weight percent. Those with skill in the art will appreciate that the concentration of the long chain alcohol will vary depending on various factors such as the dosage desired, the serving size and the solubility of the long chain alcohol in a particular oil.

One advantage of the present invention is that the long chain alcohol remains stable in the edible oil. As used herein, stable is understood to mean that the long chain alcohol does not precipitate, crystallize out, or separate when dissolved in the edible oil .

Another advantage of the present invention is that the viscosity of the policosanol-enriched oil is such that the admixture remains suitable for many applications. Unlike other disclosures, the present invention does not have to be made into a high viscosity paste before being incorporated in a comestible. The long chain alcohol/edible oil mixture has a viscosity of less than about 200 centipoise, preferably from about 10 to about 150 and most preferably from 50 to about 130 centipoise. The viscosity is measured at 70 °F using a Brookfield Viscometer Model DV-II*, spindle #2 at 60 revolutions per minute for 10 seconds.

Once the long chain alcohol has been suspended or dissolved into the oil matrix, those with skill in the art will readily understand how to incorporate the long chain alcohol/oil matrix into food products designed to lower cholesterol. The long chain alcohol/oil preparations can be used as a spray oil for cookies and crackers or can be used to formulate a number of cholesterol lowering food products including salad dressings, mayonnaise dressings, nutrition bars, beverages, juices, low fat ice creams, yogurts and frozen yogurts, non-dairy creamers, cheese spreads, milk products, confectioneries, chocolate-containing products such as cakes and cookies, margarine, and other spreads suitable for application on breads and the like. The long chain alcohol/oil preparations can also be formulated into pharmaceutical preparations, including tablets, soft gelatin capsules, especially those containing liquid formulations, such as suspensions, emulsions, solutions and the like.

The present invention can be provided in foods in which water is the continuous phase, such as salad dressings and mayonnaise. In a preferred embodiment of the invention the long chain alcohol/edible oil product of the present invention is incorporated into a product which has a continuous oil phase such as spreads and margarines. The long chain alcohol typically comprises from about 0.0001% to about 0.4% of the comestible product, preferably from about 0.007 to about 0.14 and most preferably from about 0.018 to about 0.071 weight percent of the comestible product.

Typically the level of the long chain alcohol is from 0.1 to about 100 milligrams/servings; preferably from about 0.5 to about 20 milligrams/serving and most preferably from about 2 to about 10 milligrams/servings.

The present invention provides an edible oil/ long chain alcohol mixture that does not require the incorporation of high levels of linolenic acid in the edible oil as was previously disclosed in the art. Further the present invention does not require the addition of triglycerides, particularly C_8-C_{10} triglycerides; or other surfactants or emulsifiers in order to form the admixture. Because the edible oil/long chain alcohol does not need to incorporate these other agents, the admixture can be

more readily formulated into other comestible products. Substantially free as used herein is understood to mean less than 1.0 weight percent, preferably less than 0.5 and most preferably less than 0.1 weight percent.

5   The comestible product of the present invention can be used to reduce the cholesterol level of vertebrates that consume the comestible. Vertebrates include reptiles, mammals, fish and the like, with humans being most preferred.

       The following examples are provided as specific embodiments of the present invention.
10   Other modifications of this invention will be readily apparent to those skilled in these arts without departing from the scope of the present invention.

Example 1

       One percent policosanol in a vegetable oil was prepared by adding 2.0 g policosanol
15   (CHOLESSTANOL (95 % pure sugarcane wax material from Garuda International)) to 198.0 g soybean salad oil in a 400-ml PYREX glass beaker. The beaker was placed in a waterbath on a stove. The stove was turned on and the soybean oil/policosanol mixture was stirred gently by hand with a stainless steel spatula. The policosanol/soybean oil dispersion was heated and stirred until policosanol melted and solubilized in the oil at 160 - 180 °F. The viscosity of the policosanol
20   soybean oil preparation was measured at 170, 120, 80 and 70 °F using the Brookfield Viscometer Model DV-II$^+$, Spindle #2 @ 60 rpm for 10 seconds. This viscosity data is presented in Table 1. Table 1 also presents results on soybean salad oil preparations containing 0, 0.1, 0.2, 0.4 and 0.6 weight % policosanol made by similar processes.

25   The results showed no significant differences between the viscosities of the samples at 120 °F and also at 176 °F regardless of the policosanol concentration. However, at 80 and 70 °F, the viscosities of the samples increased as the concentration of policosanol in the oil samples increased. The samples were stored at room temperature and observed the next day. The policosanol preparations developed translucent gel-like precipitates. After a few days at room temperature, the
30   gel-like materials developed layers and gel-like precipitates. The gel-like precipitates dissolved when the samples were heated to about 180°F.

Table 1. Effect of Policosanol Concentration on Viscosity of Soybean Oil

% Policosanol Concentration	Viscosity @ 176 °F	Viscosity @ 120 °F	Viscosity @ 80 °F	Viscosity @ 70 °F
0	15.0 cP	26.0 cP	43.3 cP	59.5 cP
0.10	14.5 cP	27.0 cP	43.5 cP	64.5 cP
0.20	14.5 cP	28.0 cP	46.5 cP	82.0 cP
0.40	15.0 cP	28.0 cP	49.5 cP	119.0 cP
0.60	15.0 cP	28.0 cP	53.5 cP	112.0 cP
1.00	14.5 cP	28.0 cP	105.0 cP	129.0 cP

Example 2

A policosanol preparation from the preceding example containing 1.0 % policosanol in
5   soybean oil was used to produce cholesterol lowering regular and light (reduced fat) margarine
spreads containing plant stanol esters. The formulations are shown in Table 2. The oil phase
ingredients, liquid soy bean oil (#9196 Ventura) and partially hydrogenated soybean oil (# 9494
Ventura), Canola oil, plant stanol esters, monoglycerides, lecithin and hexaglycerols were blended
together in a margarine emulsion tank. The blend was mixed slowly and heated to 160 °F to melt
10 into a clear liquid oil blend. The policosanol preparation, butter flavor, vitamins A & D blend and
beta-carotene were added and blended into the oil phase.

The aqueous phase was prepared by blending potassium sorbate, ethylenediaminetetra acetic
acid (EDTA), citric acid and salt in the water in an aqueous phase tank or in a stainless steel
15 container. While stirring the oil phase at high speed, about 800 rpm, the aqueous phase was poured
slowly into the oil phase to produce the margarine spread emulsion at approximately 130 ± 5 °F.
The margarine was prepared by processing the emulsion through a scrape surface heat exchanger
(A-unit) and then through a pin worker (B-unit) and finally through a filler unit. The finished
margarine spread was filled into suitable containers. The cooling system was adjusted during the
20 processing of the margarine spread emulsion to maintain the temperature of the finished spread at
the filler unit at about 40 – 60 °F. The margarine spreads processed as indicated exhibited physical
and sensory properties characteristic of regular and light margarine spreads.

Table 2. Composition of a Typical Cholesterol-Lowering Margarine Spread Containing Policosanol.

Oil Phase Ingredients	Regular Margarine Spread	Light Margarine Spread
	Wt. Pounds	Wt. Pounds
Liquid Soybean Oil	7.44225	23.64125
Partially Hydrogenated Soybean Oil	11.00000	0
Liquid Canola Oil	30.00000	0
Plant Stanol Esters (Raisio)	21.55000	21.55000
Mono-glycerides	0.30000	0.40000
Lecithin	0.20000	0.30000
Hexaglycerol Distearate, POLYALDO 6-2-S (Lonza)	0.10000	0.10000
Hexaglycerol Mixed Esters, CAPROL ET (A.C. Humko)	0	0.10000
Butter Flavor (Firmenich)	0.05000	0.05000
Vitamin A &D Blend (Roche)	0.00625	0.00625
Beta-Carotene	0.00150	0.00250
Policosanol/Oil Blend, (1:99 w/w) (CHOLESSTANOL Policosanol from Garuda International)	4.35000	4.35000
Aqueous Phase Ingredients		
Water	22.88550	47.38300
Salt	2.00000	2.00000
Citric Acid	0.00750	0.01000
Calcium Disodium EDTA	0.00700	0.00700
Potassium Sorbate	0.10000	0.10000
TOTAL	100.00000	100.00000

5   Both the regular and light margarine spreads contained approximately 3.5 milligrams of policosanol per 8 gram serving size.

Example 3

The policosanol preparation, 1.0 % policosanol in soybean oil, was used to prepare ranch,

10   French, creamy Italian and thousand island dressings containing plant stanol esters.   Table 3 showed the composition of a ranch dressing produced. The process for preparing the ranch dressing

in the pilot plant involved the following processing steps. The preservatives (potassium sorbate and sodium benzoate) and EDTA were dissolved in the dressing emulsion tank on a pilot plant size Charlotte Colloid Mill unit. KELTROL T xanthan gum and KELCOLOID LVF (both from Kelco) were dispersed in a portion of the soybean oil (one part gums and 2 - 5 parts oil). The gum
5 dispersion was hydrated in the water for 10 minutes using medium speed agitation. This was followed by blending in the vinegar and lemon juice, sugar, salt, ranch seasonings, buttermilk solids and titanium dioxide. After mixing the blend at high speed for 10 minutes, the polysorbates were melted and added with the liquid egg yolk and mixed for about one minute. The policosanol oil blend was mixed into the salad oil. The stanol esters (if present) and CAPROL ET (A. C. Humko)
10 were added to the soybean salad oil and the mixture was heated to approximately 130 °F to melt and dissolve CAPROL and stanol esters. While mixing the aqueous phase blend at high speed, the oil blend containing stanol esters (if present), CAPROL ET, policosanol oil blend, vitamin E and tocopherol preparation were added slowly to form the dressing emulsion. The coarse emulsion produced was then milled through a colloid mill with 0.02" gap opening. After the viscosity,
15 titratable acidity, salt and pH were determined and approved, the milled dressing was pumped through a filling unit and bottled.

Table 3. Compositions of Typical Cholesterol-Lowering Ranch Dressings Containing Policosanol with or without Stanol Esters

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Ingredient Composition	With Stanol Esters Weight (Pounds)	Without Stanol Ester Weight (Pounds)
Water	33.0807	36.6479
Vinegar, 120 Grain, White distilled	7.0000	7.0000
Sugar, Fine Granulated	4.9000	4.9000
Ranch Seasoning #139 (Ventura)	4.2000	4.2000
Cultured Buttermilk Solids #64414 (Armour)	1.6000	1.6000
Salt	0.7000	0.7000
Calcium Disodium EDTA	0.0060	0.0060
Egg Yolk, Liquid, 10 % Salt	0.3600	0.3600
KELTROL T Xanthan Gum (Kelco)	0.3500	0.3500
Polysorbate 60, Tween 60	0.3000	0.3000
Lemon Juice Concentrate, 400 GPL	0.2500	0.2500
KELCOLOID LVF, (Kelco)	0.1750	0.1750

Polysorbate 80, TWEEN 80	0.1600	0.1600
Titanium Dioxide	0.1400	0.1400
Potassium Sorbate	0.0800	0.0800
Sodium Benzoate	0.0800	0.0800
Vitamin E Acetate (Roche)	0.0183	0.0183
Policosanol/soybean oil blend (1:99 w/w) (CHOLESSTANOL policosanol from Garuda International)	1.2000	1.2000
DL-Alpha-Tocopherol (Roche)	0.0082	0.0082
Calcium Disodium EDTA	0.0060	0.0060
Paprika Oleoresin 1000 ASTA	0.0019	0.0019
Soybean Oil, Salad Oil	38.8186	41.1967
Stanol Esters (Raisio)	5.9453	0.0000
CAPROL ET (A. C. Humko)	0.6200	0.6200
TOTAL	100.0000	100.0000

Both dressings contained approximately, 3.5 milligram of policosanol per 30 gram serving size.